Complete Summary

GUIDELINE TITLE

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 2: assessment of functional outcome.

BIBLIOGRAPHIC SOURCE(S)

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 2: assessment of functional outcome. J Neurosurg Spine 2005 Jun;2(6):639-46. [38 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Degenerative disease of the lumbar spine including acute and chronic low-back pain, lumbar stenosis, and lumbar disc disease

GUIDELINE CATEGORY

Technology Assessment

CLINICAL SPECIALTY

Internal Medicine
Neurological Surgery
Neurology
Orthopedic Surgery
Physical Medicine and Rehabilitation

INTENDED USERS

Managed Care Organizations
Physicians

GUIDELINE OBJECTIVE(S)

To identify valid, reliable, and responsive measures of functional outcomes after lumbar fusion for degenerative disease

TARGET POPULATION

Patients with degenerative disease of the lumbar spine treated with lumbar fusion

INTERVENTIONS AND PRACTICES CONSIDERED

1. Measurement of functional outcome in patients with degenerative disease of the lumbar spine treated with lumbar fusion using the following instruments: The Spinal Stenosis Survey of Stucki, Waddell–Main Questionnaire, Roland-Morris Disability Questionnaire (RMDQ), Dallas Pain Questionnaire (DPQ), Quebec Pain Disability Scale (QPDS), Sickness Impact Profile (SIP), Million Scale, Low back Pain Rating (LBPR) Scale, Oswestry Disability Index (ODI), the Short Form–12, the Japanese Orthopaedic Association (JOA) system, the Curtain Back Screening Questionnaire (CBSQ), and the North American Spine Society Lumbar Spine Outcome Assessment Instrument
2. Assessment of patient satisfaction

MAJOR OUTCOMES CONSIDERED

- External and internal reliability, validity, and responsiveness of outcomes instruments for assessment of functional disability
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A computerized search of the National Library of Medicine database of the literature published between 1966 and 2003 was performed. A search using the subject heading "lumbar fusion" yielded 3708 citations. The following subject headings were combined: "lumbar fusion and outcomes." Approximately 204 citations were acquired. Only citations in English were selected. A search of this set of publications with the key words "functional outcome" and "satisfaction" resulted in 107 matches. Alternative searches included each disability index by name. Titles and abstracts of the articles were reviewed and clinical series dealing with adult patients treated with lumbar fusion for degenerative lumbar disease were selected for detailed analysis. Additional references were culled from the reference lists of remaining articles. Among the articles reviewed, 30 studies were included that dealt with lumbar fusion, functional outcomes, and satisfaction surveys. Nineteen of these articles were studies in which the authors examined the reliability of functional outcome measures. In another seven articles investigators examined the utility of these functional outcome measures in the setting of lumbar fusion. Two articles were overviews on functional outcome and lumbar degenerative disease. All papers providing Class I medical evidence are summarized in Table 1 in the original guideline document.

NUMBER OF SOURCE DOCUMENTS

30 studies

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classes of Evidence

Class I Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials

Class II Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials

Class III Evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed randomized controlled trials

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The group culled through literally thousands of references to identify the most scientifically robust citations available concerning each individual topic. Not every reference identified is cited. In general, if high-quality (Class I or II) medical evidence was available on a particular topic, poorer-quality evidence was only briefly summarized and rarely included in the evidentiary tables. If no high-quality evidence existed, or if there was significant disagreement between similarly classified evidence sources, then the Class III and supporting medical evidence were discussed in greater detail. If multiple reports were available that provided similar information, a few were chosen as illustrative examples.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In January 2003, a group was formed at the request of the leadership of the Congress of Neurological Surgeons (CNS) by the executive committee of the American Association of Neurological Surgeons/CNS Joint Section on Disorders of the Spine and Peripheral Nerves to perform an evidence-based review of the literature on lumbar fusion procedures for degenerative disease of the lumbar spine and to formulate treatment recommendations based on this review. In March 2003, this group was convened. Invitations were extended to approximately 12 orthopedic and neurosurgical spine surgeons active in the Joint Section or in the North American Spine Society to ensure participation of nonneurosurgical spine surgeons. The recommendations that were developed represent the product of the work of the group, with input from the Guidelines Committee of the American Association of Neurological Surgeons/CNS and the Clinical Guidelines Committee of North American Spine Society.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Standards Recommendations of the strongest type, based on Class I evidence, reflecting a high degree of clinical certainty

Guidelines Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

Options Recommendations based on Class III evidence reflecting unclear clinical certainty

COST ANALYSIS

Lumbar fusion may be associated with a high short-term cost, especially if instrumentation is placed; however, there appear to be long-term economic benefits associated with lumbar fusion including resumption of employment. To describe the economic impact of lumbar fusion for degenerative disease adequately, it is important to define the patient population treated with fusion and

to compare efficacy as well as the costs of other treatment alternatives. Any such analysis should include both short- and long-term costs and benefits.

See "Part 3: assessment of economic outcome" in the "Availability of Companions Documents" field for the complete analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The committee presents data that have been reviewed by the major organizations representing neurological surgery and orthopedic surgery. The Board of Directors of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) Executive Committee have reviewed these Lumbar Fusion Guidelines and formally voted their approval. In addition, input and approval was received and greatly appreciated from the AANS/CNS Guidelines committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (standards, guidelines, and options) and classes of evidence (I–III) are defined at the end of the "Major Recommendations" field.

Standards. It is recommended that functional outcome be measured in patients treated for low-back pain due to degenerative disease of the lumbar spine by using reliable, valid, and responsive scales. Examples of these scales in the low-back pain population include the following: The Spinal Stenosis Survey of Stucki, Waddell–Main Questionnaire, Roland-Morris Disability Questionnaire (RMDQ), Dallas Pain Questionnaire (DPQ), Quebec Pain Disability Scale (QPDS), Sickness Impact Profile (SIP), Million Scale, Low Back Pain Rating (LBPR) Scale, Oswestry Disability Index (ODI), the Short Form–12, the Japanese Orthopaedic Association (JOA) system, the Curtain Back Screening Questionnaire (CBSQ), and the North American Spine Society Lumbar Spine Outcome Assessment Instrument.

Guidelines. There is insufficient evidence to recommend a guideline for assessment of functional outcome following fusion for lumbar degenerative disease.

Options. Patient satisfaction scales are recommended for use as outcome measures in retrospective case series, where better alternatives are not available. Patient satisfaction scales are not reliable for the assessment of outcome following intervention for low-back pain.

Summary

Functional disability secondary to acute low-back pain, chronic low-back pain, lumbar stenosis, and lumbar disc disease may be reliably and validly assessed using functional outcome surveys that are valid, reliable, and responsive. Outcome instruments supported by Class I and Class II medical evidence for the evaluation of low-back pain include the Spinal Stenosis Survey of Stucki, Waddell-Main, Roland-Morris Disability Questionnaire, Dallas Pain Questionnaire, Quebec Pain Disability Scale, Sickness Impact Profile, Million Scale, Low Back Pain Rating Scale, Oswestry Disability Index, and the Curtain Back Screening Questionnaire. Many of these outcome measures have been applied to patients who have been treated with lumbar fusion for degenerative lumbar disease and have proven to be valid and responsive; however, the reliability of these instruments has never been specifically assessed in the lumbar fusion patient population. Patient satisfaction surveys have been used to measure outcome following lumbar fusion. Their usefulness resides in their insight into patient attitudes toward the treatment experience but is limited because of their inability to measure responsiveness and the lack of information on their reliability.

Definitions:

Grades of Recommendation

Standards Recommendations of the strongest type, based on Class I evidence reflecting a high degree of clinical certainty

Guidelines Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

Options Recommendations based on Class III evidence reflecting unclear clinical certainty

Classes of Evidence

Class I Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved assessment of functional disability in patients with degenerative disease of the lumbar spine treated with lumbar fusion

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The strength of an evidence-based document is only as strong as the foundation on which it is built. This comprehensive document chronicles the state of scientific information in 2005. Many of the published reviews presented flawed results due to poorly defined outcome measures, inadequate numbers of patients, and comparison of dissimilar treatment groups. These studies of "apples and oranges" gleaned little scientific information; therefore, for the purpose of this review, the authors have discarded Class III studies whenever stronger scientific evidence was available. The result is that most of the published studies on lumbar fusion were not included on this document. When Class I or II scientific evidence was available, standards and guidelines were formulated; however, in most cases, the scientific data were only adequate to support recommendations for treatment options. The aforementioned results do not detract from the importance of this document; rather, the need for the neurosurgical community to design and complete prospective randomized controlled studies to answer the many lingering clinical questions with rigorous scientific power can clearly be seen. As more data continue to be accumulated, revisions of this document will be needed.
- Although the functional outcome instruments discussed in this review appear valid and responsive in the low-back pain patient population, their external reliability has not been confirmed in the clinical setting of lumbar fusion. This may be important for the comparison of different lumbar fusion techniques. Another key issue appears to be the timing of administration of the outcomes instruments. The aforementioned functional outcome measures appear to be responsive both initially and over a few years. Whether the benefits associated with any sort of intervention for low-back pain are durable beyond this period has not been established.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 2: assessment of functional outcome. J Neurosurg Spine 2005 Jun;2(6):639-46. [38 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jun

GUIDELINE DEVELOPER(S)

American Association of Neurological Surgeons - Medical Specialty Society
Congress of Neurological Surgeons - Professional Association

SOURCE(S) OF FUNDING

This project was funded entirely by a grant from AANS/CNS Section on Disorders of the Spine. No funding was received from any commercial entity to support the production or publication of these guidelines.

GUIDELINE COMMITTEE

Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (CNS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Daniel K. Resnick, MD; Tanvir F. Choudhri, MD; Andrew T. Dailey, MD; Michael W. Groff, MD; Larry Khoo, MD; Paul G. Matz, MD; Praveen Mummaneni, MD; William C. Watters III, MD; Jeffery Wang, MD; Beverly C. Walters, MD, MPH; Mark N. Hadley, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

North American Spine Society - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: Resnick@neurosurg.wisc.edu.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction to the guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. 2005 Jun. 1 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 1: introduction and methodology. 2005 Jun. 2 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 3: assessment of economic outcome. 2005 Jun. 6 p. Available in Portable Document Format (PDF) from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site.

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: Resnick@neurosurg.wisc.edu.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 4, 2007. The information was verified by the guideline developer on January 29, 2007.

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